1: J Clin Oncol. 1991 Nov;9(11):2021-6. Related Articles, Links

Treatment of chemotherapy-induced anemia with recombinant human erythropoietin in cancer patients.

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Thirty patients with chemotherapy-induced anemia were treated with recombinant human erythropoietin for 4 weeks. In this dose-escalation study, cohorts of five to eight patients were treated per dose level. The doses of erythropoietin were 25, 50, 100, 200, or 300 IU/kg/d given intravenously for 5 days each week. Of 30 patients, 15 (50%) had a greater than 10% increase of their hemoglobin (Hb) values and were considered responders. At the two highest dose levels, 11 of 13 patients (85%) responded. In the 15 responding patients, the mean Hb level increased by 1.7 g/dL from baseline compared with an average decrease of 1.5 g/dL in the previous cycles of chemotherapy without erythropoietin administration. Recombinant human erythropoietin is effective in ameliorating chemotherapy-induced anemia when administered in adequate doses.

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- Clinical Trial

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☐ 1: J Natl Cancer Inst. 1993 May 19;85(10):801-6. Related Articles, Links

Recombinant human erythropoietin therapy for anemic cancer patients on combination chemotherapy.

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BACKGROUND: Patients with advanced cancer frequently experience clinically significant anemia, which is often exacerbated by myelosuppressive chemotherapy. Consistent with the anemia of chronic disease, studies have documented serum erythropoietin levels that are inappropriately low for the degree of anemia in cancer patients. Myelosuppressive chemotherapy impairs erythropoiesis, which may not fully recover between treatment cycles. Recombinant human erythropoietin (rHuEPO) has been used safely and effectively to treat anemia in AIDS patients receiving zidovudine (AZT) and in patients with chronic renal failure. PURPOSE: This study was designed to evaluate the clinical role of rHuEPO in reducing symptomatic anemia in patients with advanced cancer who were receiving myelosuppressive chemotherapy (excluding cisplatin). METHODS: We studied 153 anemic cancer patients receiving cyclic combination chemotherapy in a prospective multicenter, double-blind, placebo-controlled trial. The patients were randomly assigned to receive either rHuEPO (150 U/kg) or placebo subcutaneously three times a week for a maximum of 12 weeks or until the hematocrit level increased to 38%-40%. If the hematocrit reached this target level before 12 weeks, the rHuEPO dose could be reduced to maintain the hematocrit at that level for the duration of the study. Response to rHuEPO therapy was assessed by measuring changes in hematocrit level, transfusion requirements, and quality of life. Quality-of-life assessment was based on patients' responses to questionnaires before and after the courses of therapy. RESULTS: The increase in hematocrit in the rHuEPO-treated group compared with hematocrit in the placebo-treated group was statistically significant ($P = .0001$) as measured by percentage point of change from baseline to final evaluation, by an increase in hematocrit level of six percentage points or more unrelated to transfusion, and by a rise in hematocrit level to 38% or more unrelated to transfusion. There was a trend toward the reduction in mean units of blood transfused per patient during months 2 and 3 of therapy combined in rHuEPO-treated patients compared with placebo-treated patients (0.91 U versus 1.65 U; $P = .056$). In addition, rHuEPO-treated patients experienced a statistically significant improvement in energy level and ability to perform daily activities ($P < \text{or} = .05$). The two treatment groups showed no statistically significant differences in toxic effects except for increased incidence of diaphoresis ($P < .05$) and diarrhea ($P = .05$) in the rHuEPO-treated group. CONCLUSIONS: We conclude that rHuEPO is safe and effective for reversing anemia